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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,289	06/16/2005	Gera Neufeld	29432	5166
<div><div>7590</div><div>07/27/2007</div><div>c/o Anthony Castorina Suite 207 2001 Jefferson Davis Highway Arlington, VA 22202</div></div>				
<div>EXAMINER</div> <div>HOWARD, ZACHARY C</div>				
<div>ART UNIT</div> <div>PAPER NUMBER</div> <div>1646</div>				
<div>MAIL DATE</div> <div>DELIVERY MODE</div> <div>07/27/2007</div> <div>PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,289

Applicant(s)

NEUFELD, GERA

Examiner

Zachary C. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 1-23 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-3, drawn to isolated polypeptides.

Group II, claims 4-10, drawn to isolated polynucleotides and a nucleic acid constructs comprising said polynucleotides.

Group III, claims 14 and 20, drawn to a method of promoting re-endothelialization or preventing and/or treating restenosis in a tissue by administering a polypeptide.

Group IV, claims 15-17 and 21-23, drawn to a method of promoting re-endothelialization or preventing and/or treating restenosis in a tissue by administering a polynucleotide.

Note: Claims 11-13, 18 and 19 are linking claims that link Inventions III and IV (see below). According to Office practice, the linking claims are not listed with the groups detailed above.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-IV appears to be that they all relate to an isolated "VEGF₁₄₅ polypeptide" that is "devoid of a VEGFR-1 binding activity". The prior art appreciates that VEGF₁₄₅ is one of several splice variants of VEGF (Poltorak et al, 1997. Journal of Biological Chemistry. 272(11): 7151-7158). The art appreciates that

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VEGFR-1 is also known as Flt1 (as compared with VEGFR-2, which is also known as Flk1 or KDR).

With respect to VEGF₁₄₅ polypeptide variants encompassed by the claims, the specification teaches, "as used herein the term VEGF₁₄₅ polypeptide refers to the vascular endothelial growth factor isoform 145 (VEGF₁₄₅) protein such as the human VEGF₁₄₅ (GenBank Accession number: NP_003367) which is set forth by SEQ ID NO: 3" (pg 6, lines 31-33). The specification further teaches that, "In order to produce a VEGF₁₄₅ polypeptide devoid of VEGFR-1 binding activity ... the coding sequence of the VEGF₁₄₅ needs to be modified in such a way that the VEGFR-1 binding domain is inactivated." As such, the specification provides an example of a VEGF₁₄₅ polypeptide variant encompassed by the claims, but does not place any limitations on the number of mutations present.

The claims recited that the polypeptide is "devoid of a VEGFR-1 binding activity". The term "devoid" indicates a complete absence. However, the exemplary polypeptide disclosed in the specification retains a degree of VEGFR-1 binding activity even if it is 1900-fold less than the wild type protein. As such, the phrase "devoid of a VEGFR-1 binding activity" has been interpreted to encompass any polypeptide that has less than full VEGFR-1 binding activity (i.e., is devoid of some degree of binding).

The prior art teaches a VEGF polypeptide with reduced Flt1 binding due to mutation of residue 63 or 65 (see Table I on page 29825 of Li et al, 2000. Journal of Biological Chemistry. 275(38): 29823-29828). This polypeptide consists of residues 1-109 of VEGF with either of the indicated mutations at residue 63 or 65. As compared with wild type VEGF₁₄₅, this protein includes a truncation of residues 110-145. However, as set forth above, the instant claims encompass VEGF₁₄₅ polypeptide variants with multiple mutations. As such, the polypeptide taught by Li et al is encompassed by the claims of Group I.

Therefore, the technical feature linking the inventions of group I-IV does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Linking Claims

Claims 11-13, 18 and 19 link(s) inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 11-13, 18 and 19. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646